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February 18, 2005

CERTIFICATE OF MAILING 37 C.F.R. 1.8

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February 18, 2005

Date

David L. Parker

MS AMENDMENT

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

RE: *U.S. Patent Application No. 10/801,277 entitled "METHODS OF TREATING AUTOIMMUNE DISEASES USING TYPE ONE INTERFERONS" - Staley A. Brod*
Our reference: CLFR:115USC1
Client reference: D5716CIP4/C

Sir:

Enclosed for filing in the above-referenced patent application is an Information Disclosure Statement, Form PTO-1449, and references A1-A7, B1-B3, C1-C3, C6-C13, C16-C18, C21, C23-C25, C27-C30, C32-C37, C40-C46, and C49.

No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to the enclosed materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/CLFR:115USC1.

Please date stamp and return the enclosed postcard evidencing receipt of these materials.

Respectfully submitted,

David L. Parker
Reg. No. 32,165

DLP/kvp

Encl.: as noted



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Staley A. Brod

Serial No.: 10/801,277

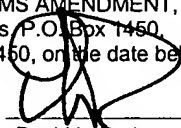
Filed: March 16, 2004

For: METHODS OF TREATING
AUTOIMMUNE DISEASES USING TYPE
ONE INTERFERONS

Group Art Unit: 1761

Examiner: Unknown

Atty. Dkt. No.: CLFR:115USC1

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| February 18, 2005 |  |
| Date | David L. Parker |

INFORMATION DISCLOSURE STATEMENT

MS AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

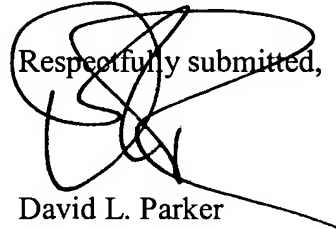
In accordance with 37 C.F.R §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be

an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/CLFR:115USC1.

This application is a continuation-in-part application of Serial No. 08/946,710, filed October 8, 1997 which is a continuation-in-part application of Serial No. 08/631,470, filed April 12, 1996 which is a continuation-in-part application of Serial No. 08/408,271, filed March 24, 1995 which is a continuation-in-part application of Serial No. 08/226,631, filed April 12, 1994 and is relied upon for an earlier filing date under 35 U.S.C. § 120. In accordance with Rule 37 C.F.R. § 1.98(d) only copies of those documents not previously cited and submitted to the Patent and Trademark Office in the above referenced prior application Serial Numbers are enclosed for the convenience of the Examiner.

Applicant respectfully requests that the listed documents be made of record in the present case.

Respectfully submitted,


David L. Parker
Reg. No. 32,165
Attorney for Applicant

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Date: February 18, 2005

Form PTO-1449 (modified)

Atty. Docket No.

CLFR:115USC1

Serial No.

10/801,277

List of Patents and Publications for Applicant's

Applicant

Staley A. Brod

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Filing Date:

March 16, 2004

Group:

1761

U.S. Patent Documents

See Page 1

Foreign Patent Documents

See Page 1

Other Art

See Page 1

U.S. Patent Documents

| Exam. Init. | Ref. Des. | Document Number | Date | Name | Class | Sub Class | Filing Date of App. |
|-------------|-----------|-----------------|----------|---------|-------|-----------|---------------------|
| | A1 | 4,409,243 | 10/11/83 | Lieb | 424 | 330 | 11/9/81 |
| | A2 | 4,462,985 | 7/31/84 | Cummins | 424 | 85 | 9/7/82 |
| | A3 | 4,497,795 | 2/5/85 | Cummins | 424 | 85.6 | 12/13/82 |
| | A4 | 5,019,382 | 5/28/91 | Cummins | 424 | 85.4 | 1/17/90 |
| | A5 | 5,093,338 | 3/3/92 | Byrne | 514 | 291 | 4/23/91 |
| | A6 | 5,624,895 | 4/29/97 | Sobel | 514 | 8 | 2/18/94 |
| | A7 | 5,780,021 | 7/14/98 | Sobel | 424 | 85.4 | 3/5/93 |

Foreign Patent Documents

| Exam. Init. | Ref. Des. | Document Number | Date | Country | Class | Sub Class | Translation Yes/No |
|-------------|-----------|-----------------|----------|---------|-------|-----------|--------------------|
| | B1 | WO 94/20122 | 9/15/94 | WIPO | | | English |
| | B2 | WO 96/28183 | 9/19/96 | WIPO | | | English |
| | B3 | WO 83/03411 | 10/13/83 | WIPO | | | English |

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

| Exam. Init. | Ref. Des. | Citation |
|-------------|-----------|--|
| | C1 | "Interferon beta-1b is effective in relapsing-remitting multiple sclerosis. I. Clinical results of a multicenter, randomized, double-blind, placebo-controlled trial. The IFNB Multiple Sclerosis Study Group," <i>Neurology</i> 43:655-661. 1993. |
| | C2 | Bayley <i>et al.</i> , "The transmucosal absorption of recombinant human interferon-alpha B/D hybrid in the rat and rabbit," <i>J. Pharm. Pharmacol.</i> 47(9):721-724. 1995. |
| | C3 | Bocci <i>et al.</i> , "Is interferon effective after oral administration? The state of the art." <i>J. Biol. Regul. Homeos. Agents</i> , 4(2):81-83, 1990. |
| | C4 | Bocci, "Absorption of cytokines via oropharyngeal-associated lymphoid tissues," <i>Clin Pharmacokinet</i> , 21(6):411-417, 1991. |

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EXAMINER:

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EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

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|---|---|----------------------------------|--------------------------|
| Form PTO-1449 (modified) | | Atty. Docket No. CLFR:115USC1 | Serial No. 10/801,277 |
| List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) | | Applicant Staley A. Brod | |
| | | Filing Date: March 16, 2004 | Group: 1761 |
| U.S. Patent Documents <i>See Page 1</i> | Foreign Patent Documents <i>See Page 1</i> | Other Art <i>See Page 1</i> | |

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| | C5 | Bocci, "Immunomodulators as local hormones: new insights regarding their clinical utilization," <i>Journal of Biological Response Modifiers</i> , 4:340-352, 1985. |
| | C6 | Bosio <i>et al.</i> , "Efficacy of low-dose oral use of type I interferon in cytomegalovirus infections in vivo," <i>J. Interferon Cytokine Res.</i> , 19:869-876, 1999. |
| | C7 | Brod and Khan "Oral administration of IFN- α is superior to subcutaneous administration of IFN- α in the suppression of chronic relapsing experimental autoimmune encephalomyelitis," <i>J. Autoimmunity</i> , 9:11-20, 1996. |
| | C8 | Brod <i>et al.</i> , "Ingested (oral) IFN-alpha induces MxA mRNA in RRMS" (Submitted for publication) |
| | C9 | Brod <i>et al.</i> , "Ingested IFN- α has biological effects in humans with relapsing-remitting multiple sclerosis," <i>Mult. Scler.</i> , 3:1-7, 1997. |
| | C10 | Brod <i>et al.</i> , "Ingested interferon α suppresses type I diabetes in non-obese diabetic mice," <i>Diabetologia</i> , 41:1227-1232, 1998. |
| | C11 | Brod <i>et al.</i> , "Ingested interferon alpha induces Mx mRNA," <i>Cytokine</i> , 11:1-8, 1999. |
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| | C13 | Brod, "Hypothesis: multiple sclerosis is a type I interferon deficiency syndrome," <i>Proc. Soc. Exp. Biol. Med.</i> 218:278-283, 1998. |
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Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

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| | C20 | Gibson <i>et al.</i> , "Pharmacokinetics of recombinant leukocyte A interferon following various routes and modes of administration to the dog," <i>Journal of Interferon Research</i> , 5:403-408, 1985. |
| | C21 | Giron <i>et al.</i> , "Effect of interferons and poly(I):poly(C) on the pathogenesis of the diabetogenic variant of encephalomyocarditis virus in different mouse strains," <i>J. Interferon Res.</i> 8(6):745-753. 1988. |
| | C22 | Goldstein <i>et al.</i> , "Human biologic response modification by interferon in the absence of measurable serum concentrations: a comparative trial of subcutaneous and intravenous interferon- β serine," <i>Journal of the National Cancer Institute</i> , 81(14):1061-1068, 1989. |
| | C23 | Goodkin <i>et al.</i> , "Experimental therapies for multiple sclerosis: current status," <i>Cleve. Clin. J. Med.</i> , 59:63-74. 1992. |
| | C24 | Gross <i>et al.</i> , "Interferon- α with condylomata acuminata and juvenile diabetes mellitus," <i>Deutsche Medizinische Wochenschrift</i> , 111(36):1351-1355, 1986. (Abstract) |
| | C25 | Higgins <i>et al.</i> , "Suppression of experimental autoimmune encephalomyelitis by oral administration of myelin basic protein and its fragments," <i>J. Immunol.</i> 140:440-445, 1988. |
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| | C27 | Hutchison <i>et al.</i> , "Chronic recurrent aphthous stomatitis: oral treatment with low-dose interferon alpha," <i>Mol. Biother.</i> , 2:160-164, 1990. |
| | C28 | Koech <i>et al.</i> , "Efficacy of Kemron (low dose oral natural human interferon alpha) in the management of HIV-1 infection and acquired immune deficiency syndrome (AIDS)," <i>East Afr. Med. J.</i> , 67(7 Supp 2):SS64-70, 1990. |
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| | C30 | Konrad <i>et al.</i> , <i>Biological Barriers to Protein Delivery</i> , ch. 14, 409-437, ed. Audus et al. 1993. |
| | C31 | Larocca <i>et al.</i> , "Evaluation of neutralizing antibodies in patients treated with recombinant interferon- β ser," <i>Journal of Interferon Research</i> , 9(Supp 1):S51-S60, 1989. |
| | C32 | Lecce <i>et al.</i> , "Treatment of rotavirus infection in neonate and weanling pigs using natural human interferon alpha," <i>Mol. Biother.</i> 2(4):211-216, 1990. |

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| | C33 | Liu <i>et al.</i> , "Accumulation of protein O-GlcNAc modification inhibits proteasomes in the brain and coincides with neuronal apoptosis in brain areas with high O-GlcNAc metabolism," <i>J. Neurochem.</i> , 89(4):1044-1055. |
| | C34 | Mashkovskii <i>et al.</i> , "Drugs," Moscow, Meditsina, 2:389-392, 1993. |
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| | C36 | Nagler <i>et al.</i> , "Immunotherapy with recombinant human interleukin-2 and recombinant interferon-alpha in lymphoma patients postautologous marrow or stem cell transplant," <i>Blood</i> , 89:3951-5959. |
| | C37 | Owens <i>et al.</i> , "The immunology of multiple sclerosis and its animal model, experimental allergic encephalomyelitis," <i>Neurol. Clin.</i> , 13(1):51-73, 1995. |
| | C38 | Paulesu <i>et al.</i> , "Oral administration of human recombinant interferon-a2 in rats," Elsevier Science Publishers B.V. (Biomedical Division), 46:199-202, 1988. |
| | C39 | Radwanski <i>et al.</i> , "Pharmacokinetics of interferon α -2b in healthy volunteers," <i>J Clin Pharmacol</i> , 27:432-435, 1987. |
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| | C41 | Schafer <i>et al.</i> , "Interferon administered orally: protection of neonatal mice from lethal virus challenge," <i>Science</i> , 176:1326-1327, 1972. |
| | C42 | Shibutani <i>et al.</i> , "Toxicity studies of human fibroblast interferon beta (I) acute and subacute toxicity studies in mice and rats," <i>Iyakuin Kenkyu</i> , 18:571-582. (1987) (Abstract) |
| | C43 | Shim <i>et al.</i> , "Administration route dependent bioavailability of interferon- α and effect of bile salts on the nasal absorption," <i>Drug Dev. Indus. Pharm.</i> , 19:1183-1199. 1993. |
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| | C45 | Vial <i>et al.</i> , "Clinical toxicity of the interferons," <i>Drug Saf.</i> , 10(2):115-150, 1994. |
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Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

| Exam. Init. | Ref. Des. | Citation |
|----------------|--------------|---|
| | C47 | Wills <i>et al.</i> , "Pharmacokinetics of recombinant alpha A interferon following IV infusion and bolus, IM, and PO administration to African green monkeys," <i>Journal of Interferon Research</i> , 4(3):399-409, 1984. |
| | C48 | Witt <i>et al.</i> , "Absence of biological effects of orally administered interferon- β ser," <i>Journal of Interferon Research</i> , 12:411-413, 1992. |
| | C49 | Yershov <i>et al.</i> , "Interferon status in different diseases," <i>Voprosy Virusologii</i> , 35:444-448, 1990 (Russian) |

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